REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claim 73 was cancelled previously. Claims 26 and 50 have been amended to incorporate the release profiles, with exemplary support found in the original claims. Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-72 are pending in the application.

II. Double Patenting Rejection

Claims 1-26 and 31-72 stand rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-34 of U.S. Patent No. 6,908,626 to Cooper *et al.* in view of U.S. Patent No. 6,221,377 to Meyer *et al.* Applicants respectfully traverse the rejection.

Without acquiescing to the stated rationale, Applicants submit herewith a terminal disclaimer for U.S. Patent No. 6,908,626. Accordingly, the obviousness-type double patenting rejection is requested to be withdrawn.

III. Rejection of Claims under 35 U.S.C. §103

A. Claims 1-17, 26-42 and 50-67

Claims 1-17, 26-42 and 50-67 remain rejected for allegedly being obvious over WIPO Publication No. WO 93/25190 to Liversidge *et al.* ("Liversidge") or U.S. Patent No. 6,375,986 to Ryde *et al.* ("Ryde") in view of U.S. Patent No. 6,221,377 to Meyer *et al.* ("Meyer"). Applicants respectfully traverse the rejection.

Applicants maintain all arguments made in the prior responses, although not repeated in this response, that the cited art, either alone or in combination, does not teach the claimed

limitation of the release profile, which requires that the claimed composition exhibits a shorter time to T_{max} relative to the time to T_{max} of the non-nanoparticulate formulations.

With respect to the claimed features that nanoparticulate meloxicam compositions exhibit a shorter T_{max} then non-nanoparticuate compositions, the Examiner contends that although claimed, she "is unable to determine unexpected result and patentability of the present application because the comparison data [in the specification] did not show a compatible formulation for each dosage form." See Advisory Action, page 5, last five lines.

Applicants note that the independent claims require a comparison between nanoparticulate compositions and non-nanoparticulate compositions of meloxicam having the same dosage **strength** and **form**. With this requirement in mind, Applicants submit herewith a Rule 1.132 Declaration executed by Dr. Simon McGurk in support of the argument that the claimed nanoparticulate composition exhibits a shorter time to T_{max} when compared to a non-nanoparticulate composition of the same strength and dosage form.

The Declaration reports results of a non dose-adjusted study where a single 7.5 mg dose of meloxicam in different dosage forms was administered to healthy individuals. The calculated mean T_{max} values for the nanoparticulate meloxicam tablet, the non-nanoparticulate meloxicam tablet, and the commercially available meloxicam tablet (MOBIC® tablet) are set forth in the Declaration and repeated in the Table below. This Table also lists the mean T_{max} values following single oral administration to healthy individuals of 7.5 mg meloxicam suspension under fasted conditions and meloxicam non-nanoparticulate tablets under fed and fasted conditions as reported in NDA 21-530 (excerpt submitted herewith as Exhibit A, *see* pg. 5) and NDA-20-938 (excerpt submitted herewith as Exhibit B, *see* pgs. 21-25), respectively.

Nanoparticulate Dosage Forms	T_{max} (h)	T_{max} (h)	Non-nanoparticulate Dosage Forms
Declaration Tablet	1.316	3.500	Declaration Tablet
		4.750	Declaration MOBIC® Tablet
		5.1	NDA 20-938 Tablet (fasted)
		7.3	NDA 20-938 Tablet (fed)
Declaration Reconstituted Tablet (dispersion)	0.667	5.87	NDA 21-530 Oral Suspension

Error! Hyperlink reference not valid. The above Table provides a comparison of the data between compatible formulations for each dosage form. In each comparison, the claimed nanoparticulate composition exhibits a shorter time to T_{max} when compared to the time to T_{max} of the non-nanoparticulate meloxicam formulation of the same dosage form. Withdrawal of the rejection is respectfully requested.

B. Claims 18-25, 43-49 and 68-72

Claims 18-25, 43-49 and 68-72 were rejected for allegedly being obvious over Liversidge or Ryde in view of WIPO Publication No. WO 01/45706 to Desai *et al.* ("Desai") or U.S. Patent No. 5,384,124 to Courteille *et al.* ("Courteille"). Applicants respectfully traverse the rejection.

As discussed above, claim 1 is non-obvious over the cited prior art. Claims 18-25, 43-49 and 68-73 are also non-obvious because they depend either directly or indirectly from claim 1 and are read to include the limitations of claim 1. Withdrawal of the rejection of these claims is respectfully requested.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 3 2008

By _____

FOLEY & LARDNER LLP
Customer Number: 31049
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717